NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (e) (2), the repackaged *tablets of sulfadiazine and sulfamerazine* failed to bear a label containing the common or usual name of each active ingredient of the drug; and, Section 502 (f) (2), the labeling of the repackaged *tablets of sulfadiazine and sulfamerazine* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: February 11, 1953. Pleas of guilty having been entered, the court imposed a fine of $300 against Defendant Lantz and a fine of $200 against Defendant Brown.

3952. Misbranding of sulfathiazole tablets. U. S. v. Sam's Cut Rate Drugs, Inc., and Claude E. Wilson and Carl R. Miller. Pleas of nolo contendere. Fine of $100 against corporation, $100 against Defendant Miller, and $50 against Defendant Wilson, plus costs. (F. D. C. No. 33846. Sample Nos. 33549–L, 33555–L, 33556–L, 33563–L.)

INFORMATION FILED: January 22, 1953, Northern District of Illinois, against Sam's Cut Rate Drugs, Inc., Chicago, Ill., and Claude E. Wilson and Carl R. Miller, pharmacists for the corporation.

ALLEGED VIOLATION: On or about October 17, 19, and 21, 1951, while a number of *sulfathiazole tablets* were being held for sale at Sam's Cut Rate Drugs, Inc., after shipment in interstate commerce, various quantities of the tablets were repacked and dispensed without a physician's prescription, which acts resulted in the repackaged tablets being misbranded.

The corporation was charged in each of the four counts of the information with causing such acts of repacking and dispensing, and Claude E. Wilson was joined as a defendant in one count and Carl R. Miller was joined as a defendant in the other three counts of the information.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged tablets failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (1), the repackaged tablets failed to bear a label containing the common or usual name of the drug; and, Sections 502 (f) (1) and (2), the repackaged tablets failed to bear labeling containing adequate directions for use and adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: February 16, 1953. Pleas of nolo contendere having been entered, the court imposed a fine of $100 against the corporation, $100 against Defendant Miller, and $50 against Defendant Wilson, plus costs.

3953. Adulteration and misbranding of various drugs. U. S. v. 1 Bottle, etc. (F. D. C. No. 33580. Sample Nos. 18348–L to 18350–L, incl., 39891–L, 39892–L, 39894–L to 39896–L, incl.)

LIBEL FILED: September 8, 1952, District of Arizona.

ALLEGED SHIPMENT: During July 1952, from Seattle, Wash., to Yuma, Ariz., and thereafter transported to Phoenix, Ariz., via the automobile of William L. Palmer.

PRODUCT: 1 1,000-tablet bottle, 11 500-tablet bottles, and 1 400-tablet bottle of *Tablets No. 105;* 6 1,000-tablet bottles, 11 500-tablet bottles, and 1 250-tablet bottle of *Tablets No. 106;* 49 1,000-tablet bottles of *Tablets No. 146;* 11 1,000-tablet bottles and 1 500-tablet bottle of *Tablets No. 108;* 10 1,000-tablet bottles and 6 500-tablet bottles of *Tablets No. 137;* 20 1,000-capsule bottles of *Dasil Evronal capsules;* 4 1,000-tablet bottles of *Dasil Veratrum Compound tablets;* and 4 1,000-tablet bottles of *Dasil Tu-Tone capsules,* at Phoenix, Ariz.

LABEL, IN PART: "Tablets No. 105 1.25 mg. Estrogenic Substances (Water Soluble) Conjugated Estrogens (Equine) * * * Distributed by Palmer & Co. Seattle, Wash."; Tablets No. 106 0.625 mg. Estrogenic Substances (Water Soluble) Conjugated Estrogens (Equine) * * * Distributed by Palmer & Co. Seattle, Wash."; "Tablets No. 146 Dex-Amo Each Tablet Contains: Dextro Amphetamine Sulfate U. S. P. 5 mg. Amobarbital N. F. ½ gr. (32 mg.) Distributed by Palmer & Co. Seattle, Wash."; "Tablets No. 108 Each Tablet Contains Phenobarbital 15 mg. Aminophyllin 100 mg. Rutin 20 mg. * * * Distributed by Palmer & Co. Seattle, Wash."; "No. 137 Paba-Sal Each Tablet Contains Para-Aminobenzoic Acid (5 gr.) 0.3 gm. (As the Sodium Salt) Sodium Salicylate (5 gr.) 0.3 gm. Enteric Coated Distributed by Palmer & Co. Seattle, Wash."; "Capsules Dasil Evronal 1½ gr. (Sodium Aprobarbital) Palmer & Co. Distributors, Seattle, Wash."; "Dasil Veratrum Compound Tablets Each Tablet Contains: Veratrum Viride ¾ gr. Phenobarbital ¼ gr. Sodium Nitrite 1 gr."; and "Dasil Tu-Tone Vitamin D A super potency Vitamin D Capsule containing 50,000 U. S. P. units of Irradiated Ergosterol. Evron Company, Distributors, Chicago, Ill."

NATURE OF CHARGE: *Tablets No. 105.* Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess. Misbranding, Section 502 (a), the label statement "Each tablet contains 1.25 mg. of estrogens in * * * conjugated form, expressed as sodium estrone sulfate" was false and misleading as applied to the article, which contained less than the declared amount of estrogens in conjugated form. (Analysis disclosed that the article contained 0.76 mg. per tablet of conjugated estrogens, expressed as sodium estrone sulfate.)

Tablets No. 106. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess. Misbranding, Section 502 (a), the label statement "Each tablet contains 0.625 mg. of estrogens in * * * conjugated form, expressed as sodium estrone sulfate" was false and misleading as applied to the article, which contained less than the declared amount of estrogens in conjugated form. (Analysis disclosed that the article contained 0.390 mg. per tablet of conjugated estrogens, expressed as sodium estrone sulfate.)

Tablets No. 146. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess. Misbranding, Section 502 (a), the label statement "Each Tablet Contains: Dextro Amphetamine Sulfate U. S. P. 5 mg. Amobarbital N. F. ½ gr. (32 mg.)" was false and misleading as applied to the article, which contained less than the declared amounts of dextro-amphetamine sulfate and amobarbital. (Anal-

ysis disclosed that the article contained 1.12 mgs. per tablet of amphetamine sulfate and 18.3 mgs. of amobarbital.) Further misbranding, Section 502 (d), the article contained amobarbital, a habit forming derivative of barbituric acid, and the label of the drug failed to bear a statement of the quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Tablets No. 108. Misbranding, Section 502 (d), the label of the article failed to bear in juxtaposition with the name and quantity of the habit forming substance, phenobarbital, the statement "Warning—May be habit forming."

Tablets No. 137. Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the labeling failed to reveal the purposes for which the article was to be used.

Dasil Evronal capsules. Misbranding, Section 502 (d), the label of the article failed to bear in juxtaposition with the name and quantity of the habit forming substance, sodium aprobarbital, the statement "Warning—May be habit forming."

Dasil Veratrum Compound tablets. Misbranding, Section 502 (a), the label statement "Veratrum Compound Tablets" was misleading as applied to the article, which contained, in addition to veratrum, the drugs phenobarbital and sodium nitrite; and, Section 502 (d), the label of the article failed to bear in juxtaposition with the name and quantity of the habit forming substance, phenobarbital, the statement "Warning—May be habit forming."

Dasil Tu-Tone capsules. Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the labeling failed to bear a statement as to the quantity, frequency, or duration of use.

DISPOSITION: December 11, 1952. Default decree of condemnation and destruction.

3954. Misbranding of Femo capsules. U. S. v. 8,000 Capsules, etc. (F. D. C. No. 31326. Sample No. 11178-L.)

LIBEL FILED: July 9, 1951, Northern District of Ohio.

ALLEGED SHIPMENT: On or about February 21, 1951, by the Gelatin Products Div., R. P. Scherer Corp., from Detroit, Mich.

PRODUCT: 8,000 *Femo capsules* and an unknown number of labels intended for use on the article when repackaged, in the possession of the Kumfort Drug Products, trade name of the Lipton Drug Sales Co., Cleveland, Ohio. The article had been shipped in interstate commerce in a drum and had been in part repacked into cartons containing 24 capsules.

LABEL, IN PART: (Drum) "Product #53180 * * * Ingredients in each capsule: Ergot, Powdered USP XII 259.2 mg. Aloin, USP 8.1 mg. Apiol Fluid Green 290 mg. Oil Pennyroyal 28 mg. Cottonseed Oil USP q.s. 10 minims. Warning: This is a dangerous drug which may cause serious or fatal injury unless consumed under adequate and continuous medical supervision. Should not be used by individuals with high blood pressure. Excessive doses or prolonged use may cause gastric disturbances. Should not be used during pregnancy, nor by persons suffering from hemorrhoids, nor in the presence of nausea, vomiting, abdominal pains or other possible signs of appendicitis. Caution: To be dispensed only by or on the prescription of a physician"; (carton) "Femo Perles Original Formula, containing the Emmenagogues, Penny-royal, Oil Tansy, Apiol Fluid, Green, Oil Rue Adult Use